



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/505,788	02/17/2000	Richard E. Olson	PH-7076-A	7287

24348 7590 12/12/2002

BRISTOL-MYERS SQUIBB PHARMA COMPANY
PATENT DEPARTMENT
P.O. BOX 4000
PRINCETON, NJ 08543-4000

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT PAPER NUMBER

1624

DATE MAILED: 12/12/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/505,788

Applicant(s)
OLSON

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 24, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 8, 10-14, 16, 18, 20, 22, 23, and 25-56 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 10-14, 18, 20, 22, 23, 27-29, 31-36, 38, 39, 42-44, 46-51, 53, is/are rejected.
- 7) ☒ Claim(s) 6, 16, 25, 26, 30, 37, 40, 41, 45, 52, 55, and 56 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 14 6) ☐ Other:

Art Unit: 1624

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 24, 2002 has been entered.

Claims 1-4, 6, 8, 10-14, 16, 18, 20, 22, 23 and 25-56 are pending in the application.

This action is in response to applicants' amendment dated September 24, 2002. Claims 1, 10, 20 and 23 were amended and claims 27-56 are newly added.

Response to Arguments

Applicant's arguments filed September 24, 2002 have been fully considered with the following effect:

1. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections of the last office action, which are hereby **withdrawn**.

In view of the amendment dated September 24, 2002, the following new grounds of rejection apply:

Information Disclosure Statement

2. The information disclosure statement filed September 24, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or

Art Unit: 1624

that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Several of the references were not available to the Examiner and/or sent in by the applicants. It is requested that the applicants provide a copy of WO 01/60826; WO 08/48957; WO 99/42889 and the Su San Mok et al. journal article. See attached 1449 where the references listed above have lines drawn through the initials box.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4, 8, 10-14, 18, 20, 22, 23, 27-29, 31-36, 38, 39, 42-44, 46-51, 53 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 1 (and claims dependent thereon) recite the limitation "2,4-dioxo" in the proviso where ring B is 1,3,4,5,-tetrahydro-1-(Z)-5-(R¹⁰)-6,6,7,7-tetra(R¹¹)-2,4-dioxo-2H-1,5-diazepin-3-yl. There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 1624

- b) Claim 3 (and claims dependent thereon) recite the limitation " $=O$ " in the 4-position of the third structure under the definition of Ring B, i.e. the definition of R^{11} .
There is insufficient antecedent basis for this limitation in the claim.
- c) Claim 4 (and claims dependent thereon) recite the limitation " $=O$ " in the 4-position of the third structure under the definition of Ring B, i.e. the definition of R^{11} .
There is insufficient antecedent basis for this limitation in the claim.
- d) Claim 8 (and claims dependent thereon) recite the limitation " $=O$ " in the 4-position of Formula (Ie), i.e. the definition of R^{11} . There is insufficient antecedent basis for this limitation in the claim.
- e) Claim 11 recites the limitation "2,4-dioxo" in the last species. There is insufficient antecedent basis for this limitation in the claim.
- f) Claim 12 (and claims dependent thereon) recite the limitation "2,4-dioxo" in the proviso where ring B is 1,3,4,5,-tetrahydro-1-(Z)-5-(R^{10})-6,6,7,7-tetra(R^{11})-2,4-dioxo-2H-1,5-diazepin-3-yl. There is insufficient antecedent basis for this limitation in the claim.
- g) Claim 13 (and claims dependent thereon) recite the limitation " $=O$ " in the 4-position of the third structure under the definition of Ring B, i.e. the definition of R^{11} . There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 1624

- h) Claim 14 (and claims dependent thereon) recite the limitation "=O" in the 4-position of the third structure under the definition of Ring B, i.e. the definition of R¹¹. There is insufficient antecedent basis for this limitation in the claim.
- i) Claim 18 (and claims dependent thereon) recite the limitation "=O" in the 4-position of Formula (Ie), i.e. the definition of R¹¹. There is insufficient antecedent basis for this limitation in the claim.
- j) Claim 20 is vague and indefinite in that it is not known what is meant by the moiety (4-MeS-phenyl)CH₂- in the definition of Z on page 58. The applicants are reminded of the Manner of Making Amendments where a clean copy with no brackets and/or underlines should be submitted along with a marked up copy with brackets and/or underlines.

Claim Objections

4. Claims 6, 16, 25, 26, 30, 37, 40, 41, 45, 52, 55 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. None of the prior art of record nor a search in the pertinent art area teaches the compounds, compositions or method of use of the compounds of Formulae (Ic) and (Ig) as claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner

Art Unit: 1624

can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman
Primary Examiner AU 1624
December 9, 2002